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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,850	11/02/2001	Sreekumar Pillai	J6673(C)	6359

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PATENT DEPARTMENT
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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/003,850	Pillai et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 17, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 5, and 6* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 5, and 6* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2,3*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment filed July 17, 2003 has been received and entered into the file.

Claims 1-2 and 5-6 are presented for examination.

Applicant's election with traverse of Group I, claims 1-2 and 5-6 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the search and examination would not place and undue burden on Examiner. This is not found persuasive for two reasons. First, cancellation of the non-elected claims render the restriction moot. Second, the presented claims are linked only by those compounds taught as useful in Applicants' specification for practicing the invention as envisioned. To meet those claims herein presented Examiner need only provide motivations linking such claims, not those uses envisioned by the Applicants. Thus, the presented claims are broader than envisioned by Applicant and would place an undue burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither a specific class of compounds, nor specific structural features defining phytoestrogens, or retinoid boosters. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of phytoestrogens, or retinoid boosters examples are set forth, thereby failing to provide sufficient working examples. It is noted that these

examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all phytoestrogens, or retinoid boosters, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 and 5-6 are is rendered indefinite by the term retinoid boosters and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are retinoid boosters are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Examiner notes the specification is ambiguous with regard to those compounds suitable as retinoid boosters. At page 30 Applicant state "(I)t is the IC50 value that is used as a benchmark in the present invention" not reciting how this

"benchmark" might be employed for ascertaining which compounds would be envisioned as retinoid boosters in the instant claimed utility. The table on page 28 sets forth various IC50 values for "transglutaminase" activity (Examiner assumes this is actually glutamase transaminase enzymatic activity), yet the specification fails to establish, disclose, hint, or imply this level of inhibition establishing a threshold for compounds possessing retinoid booster activity. Those figures presented on page 28 and the statement on page 30 are contradictory, and ambiguous in regard to those enzyme inhibition levels required to establish a compounds as possessing retinoid booster activity. Thus, the information presented in the instant specification fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed

invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. § 103 as being unpatentable over Cohen et al, Weidenboerner et al, Mishra et al, and Jones et al, in view of Suares et al.

Cohen et al, Weidenboerner et al, Mishra et al, and Jones et al teach the claimed compounds retinoic acid, isoflavones (phytoestrogens), faresol, and clotrimazole respectively as old and well known in combination with various pharmaceutical carriers and excipients in dosage forms. These medicament are taught as useful for treating fungal infections. Claims 1-2 and 5-6, and the primary references, differ as to:

1) the concomitant employment of these medicaments,

2) administration levels of the medicaments, and

2) administration of the medicaments in separate containers.

It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-fungal agents. It would follow that the recited claims define

prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known antifungal active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed therapeutic compositions of matter.

Claim 1-2 and 5-6 require a topical pharmaceutical composition, individually packaged to provide those therapeutic benefits inherent in each composition individually. Suares et al employ a dual container system for multi composition use. Those formulations taught by Suares et al employ retinoic acid compositions useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherent in sequential application as set forth in Suares et al claim 1. The skilled artisan would have seen the separate packaging teachings Suares et al useful for individual

application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers
Primary Examiner
Art Unit 1614